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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,288	01/14/2005	Stanislaw Flasiński	1189.0235. PCUS00	5604
45607 7590 04/20/2009 HOWREY LLP C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE SUITE 200 FALLS CHURCH, VA 22042				
EXAMINER				
MEHTA, ASHWIN D				
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1638				
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04/20/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/521,288

**Applicant(s)**

FLASINSKI, STANISLAW

**Examiner**

Ashwin Mehta

**Art Unit**

1638

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1.6-11, 14, 24 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1.6-11, 14, 24 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The amendments filed January 29, 2009 were entered. Claims 1, 6-10, 11, 14, 24, and 29 are pending, and claims 2-5, 12, 13, 15-23, 25-28, and 30-34 are cancelled.
3. The rejection of claims 1, 29 and 34 under 35 U.S.C. 112, second paragraph is withdrawn in light of the claim amendments or cancellation.
4. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, over the term "divergent", is withdrawn in light of the claim amendment. In the response, Applicants argue that the specification at page 14, lines 10-18 teaches what is intended by the term "divergent", and Applicants quote "polynucleotide molecules that encode the same polypeptide where these molecules have a sequence of nucleotides of their entire length in which they are less than 85% identical, and there are no lengths of polynucleotide sequence greater than 23 nucleotides that are identical." However, the sentence at page 14, lines 10-11 states, "The term "divergent", as used herein, refers to the comparison of polynucleotide molecules that encode the same or nearly the same protein or polypeptide." That statement does not limit in any way the difference in sequence identity between the two polynucleotides. Therefore, the portion of the specification quoted by Applicants, which is from page 14, lines 15-18, is a limitation of the specification that

cannot be read into the claims. The amendment to claim 1, however, does now indicate that the artificial polynucleotide and the known polynucleotide both encode polypeptides that comprise SEQ ID NO: 15, and therefore it is clear that "divergent" indicates that the sequences of the artificial and known polynucleotides are not the same. The interpretation of "divergence", however, is not being limited to "polynucleotide molecules that encode the same polypeptide where these molecules have a sequence of nucleotides of their entire length in which they are less than 85% identical, and there are no lengths of polynucleotide sequence greater than 23 nucleotides that are identical", as this is a limitation recited in the specification, which cannot be read into the claim. The claim is being interpreted such that the artificial polynucleotide and known polynucleotide have different nucleotide sequences, but both encode polypeptides comprising SEQ ID NO: 15.

***Claim Rejections - 35 USC § 112***

5. Claims 1, 10, 11, 14, and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, for the reasons of record stated in the Office action mailed October 24, 2008. Applicant traverses in the response filed January 29, 2009. Applicant's arguments were fully considered but were not fully persuasive.

Applicant argues that claims 1, 8, 10, and 14 were amended to include a limitation pertaining to a chloroplast transit peptide operably linked to SEQ ID NO: 18 (response, page 6). However, the known polynucleotide also encodes SEQ ID NO: 15, and therefore is too must

encode a chloroplast transit peptide, operably linked to the nucleotide sequence encoding SEQ ID NO: 15, as the chloroplast is where it exerts its functional activity, as taught in the specification.

6. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is insufficient antecedent basis for the limitation, “said artificial polynucleotide molecule”.

7. Claims 1, 10, 11, and 29 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification, for the reasons stated in the Office action mailed October 24, 2008. Applicant traverses in the response filed January 29, 2009. Applicant’s arguments were fully considered but were not fully persuasive.

Applicants argue that the language “that are at least 98% identical” is deleted from the claims; claim 1 is amended to indicate that the artificial and the known polynucleotides both encode polypeptides encoding SEQ ID NO: 15; claim 10 is amended to state the artificial and known polynucleotides encode the same polypeptide (response, page 7). The amendments overcome the aspect of the rejection regarding the artificial and known polypeptides encoding different proteins. However, the amended claims do not recite the level of divergence between the known and artificial polynucleotides, and therefore encompass artificial and known

polynucleotides that are not sufficiently divergent to avoid transgene silencing. This aspect of the rejection was not addressed.

The rejection also indicated that the essential element of a chloroplast target peptide being fused to the EPSPS sequence (SEQ ID NO: 15) encoded by the artificial and known polypeptides, was omitted from the claims. The amended claims now recite that a polynucleotide encoding such a transit peptide is operably linked to the artificial polynucleotide. However, the claims do not indicate that it is also operably linked to the known polynucleotide.

***Claim Rejections - 35 USC § 103***

8. Claims 1, 6-11, 14, 24, and 29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (WO 97/46690) in combination with Barry et al. (U.S. Patent No. 5633435, issued May 27, 1997), and Murray et al. (Nucl. Acids Res. 1989, Vol. 17, pages 477-498), for the reasons stated in the Office action mailed October 24, 2008. Applicant traverses in the response filed January 29, 2009. Applicant's arguments were fully considered but were not persuasive.

Applicants argue that Drake et al. teach the use of a transgene that is divergent from a native or naturally occurring gene in that plant for the purpose of preventing silencing of the native gene, and direct attention to Examples 1-3, and argue that the abstract of Drake et al. states that their method involves the synthesis of a DNA which is altered in sequence and capable of expressing a protein ideally identical to that of a protein already expressed by a DNA already present in the organism. Applicants argue that in Drake's method, only one transgene is introduced, and the second gene is a native gene, whereas the method of instant claim is limited

to avoid transgene silencing wherein both genes are transgenes (response, page 8). However, Drake et al. does not teach that the original gene must only be a native or naturally occurring gene in the plant. While Drake et al. teach that the synthetic DNA is altered relative to a DNA already present in the organism, Drake et al. do not limit that DNA to ONLY being a native or naturally occurring gene. One of ordinary skill would have a reasonable expectation of success following the method of Drake et al. whether the DNA already present in the organism is a transgene or native gene. Applicants do not explain why the method would fail if the DNA already present was a transgene.

Applicants also argue that the artificial polynucleotide molecules of claims 6, 14, 24, and 29 are not the same as the artificial sequence disclosed in Barry et al. and is not taught in Drake et al. or Murray et al. Applicants argue that Murray et al. is a codon usage table for maize and does not teach the specific sequence of claims 6, 14, 24, and 29 (response, page 8). However, this argument does not consider the references in combination, which would result in the artificial polynucleotide encompassed by the claims, as explained in the previous Office action.

### *Summary*

9. Claims 1, 6-11, 14, 24, and 29 remain rejected.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:30 A.M to 6:00 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

April 17, 2009

/Ashwin Mehta/  
Primary Examiner, Art Unit 1638